IN THE

Supreme Court of the United States

OCTOBER TERM, 1975

No. 75-1540

NATICK PAPERBOARD CORP., *et al.*,
Petitioners,

v.

F. DAVID MATHEWS, Secretary of Health, Education and Welfare, *et al.*,
Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

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April 23, 1976

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PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

Petitioners pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the First Circuit entered in the above entitled case on November 26, 1975.

CITATION TO OPINIONS BELOW

The opinion of the United States Court of Appeals for the First Circuit dated November 26, 1975 appears as Appendix A, *infra*, and is reported at 525 F.2d 1103 (1975). The opinion of the United States District

Court for the District of Massachusetts dated March 4, 1975 appears as Appendix B, *infra*, and is reported at 389 F. Supp. 794 (1975).

JURISDICTION

The judgment of the United States Court of Appeals for the First Circuit was entered on November 26, 1975. On February 13, 1976, petitioners filed an application with this Court to extend the time within which to file this Petition from February 24, 1976 until April 23, 1976. Mr. Justice Brennan on February 17, 1976 (No. A-702) granted an extension until April 23, 1976. This Court has jurisdiction to review the decision below by writ of certiorari pursuant to 28 U.S.C. § 1254(1).

QUESTION PRESENTED

Does the Food and Drug Administration have the statutory authority to classify paper food-packaging material as a "food" as that term is defined in 21 U.S.C. § 321(f) and thus subject paper food-packaging material to seizure as a "food . . . that is adulterated."

STATUTORY PROVISIONS INVOLVED

The statutory provisions in relevant part involved herein are the following sections of Title 21 of the U.S. Code codifying the Federal Food, Drug and Cosmetic Act:

> Sec. 321(f): "The term 'food' means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."
>
> Sec. 342(a)(2)(C): "A food shall be deemed to be adulterated . . . if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title."
>
> Sec. 334(a)(1) and (b) permit seizure of: "[a]ny article of food . . . that is adulterated . . . when introduced into or while in interstate commerce."
>
> Sec. 321(s): "The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in . . . packaging . . . or holding food; . . .), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use; . . ."

STATEMENT OF THE CASE

Petitioners Natick Paperboard Corporation and Crown Paperboard Company, Inc. (hereinafter "Natick") manufacture paper packaging material from waste paper. Some of the paper packaging material Natick manufactures through this recycling process may be used as food-packaging material. Certain types of carbonless copy paper in the waste paper stocks from which the packaging material is made contains substances known as polychlorinated biphenyls ("PCB's").

Respondents, the Secretary of Health, Education and Welfare and the Commissioner of Food and Drugs (hereinafter the "FDA"), consider PCB's to be toxic substances which should not be present in excess of specified amounts in foods destined for human con-

sumption. On July 6, 1973, the FDA published a proposed regulation designed primarily to limit the presence of PCB's in food; subsection (a)(9) of this proposal prohibited PCB residues of more than 10 parts per million (ppm) in paper food-packaging material. 38 F.R. 18096, 18101-02; 21 C.F.R. § 122.10 (a)(9). Thereafter, on August 24, 1973, the FDA announced that paper food-packaging material containing PCB's in excess of 10 ppm would be considered an "adulterated" food and thus subject to seizure.[1] 38 F.R. 22794.

Natick sought a declaratory judgment[2] that the FDA's August 24, 1973 notice of seizure was promulgated without statutory authorization as it contained the erroneous legal predicate that paper food-packaging material could be classified as a "food." The district court sustained the FDA's authority to recommend the seizure of paper food-packaging material which contains PCB's in amounts greater than 10 ppm. See 389 F. Supp. 794 (D. Mass. 1975). The Court of Appeals for the First Circuit affirmed. 525 F.2d 1103. It is from that affirmance that petitioners now seek a

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[1] For purposes of this petition, petitioners do not dispute the FDA's finding that PCB's in paper food-packaging material may migrate from the packaging material to the food. The proposed regulations are not as yet final and are not directly challenged in this litigation; at issue is only the FDA's power to enforce the notice of seizure.

[2] Petitioners initially sought declaratory and injunctive relief. The district court first denied relief based upon the view it lacked power to grant the relief requested. See 367 F. Supp. 885 (D. Mass. 1973). The court of appeals reversed the district court's judgment with respect to declaratory relief and remanded for a determination on the merits of this request. See 498 F.2d 125 (1st Cir. 1974).

writ of certiorari to the Court of Appeals for the First Circuit.

REASONS FOR GRANTING THE WRIT

The rather simple distortion of the language of the Federal Food, Drug and Cosmetic Act (the "Act") sanctioned by the courts below constitutes a matter worthy of this Court's attention for two related reasons. First, the distortion permits an expansion of the FDA's jurisdiction to allow the seizure of any item which assertedly might contaminate food even though such an item is far removed from the statutory definition of food. Second, this distortion was produced by the type of judicial willingness to rewrite legislation in the hope of increased public protection, which willingness this Court has—and, in this case, should—restrain.

I. Paper Food-Packaging Materials Do Not Constitute "Food" As That Term Is Statutorily Defined

The FDA's power to order seizures is limited to "food . . . that is adulterated." 21 U.S.C. § 334(a)(1) and (b). The power to seize is thus expressly conditioned upon the statutory requirement that the item seized constitute a "food". Section 321(f) provides a lucid, easily understood definition of food as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of *any such article*." (Emphasis added.) Paper food-packaging material is obviously neither food nor drink nor chewing gum. If food-packaging material can constitute a statutorily defined "food" subject to seizure it is therefore solely because this material is an article used for a "component" of food or drink.

The Act does not define "component." Cases typically understand this term to refer to a portion of or an integral ingredient of the ultimate product. See, *e.g., Morrow Radio Manufacturing Co.* v. *United States,* 287 F.2d 502, 504 (9th Cir. 1961); *Estoppey* v. *United States,* 83 F. Supp. 840, 842 (Ct. Claims 1949). The standard dictionary definition of "component" is equally precise: "composing; constituting; entering into as a part." *Living Webster Encyclopedic Dictionary* 207 (1st ed. 1971). Food-packaging material is a container for food but surely not a part of or a component of that food. This material therefore does not fall within the third branch of the statutory definition of food. At the risk of belaboring the obvious, we do not understand the FDA to contend that paper food-packaging material is a food because of the risk that someone might eat the package.

Unfortunately, the courts below accepted the FDA's revision of the statutory definition of "food" contained in section 321(f) of the Act by adding to the three-pronged definition of food a fourth prong—"unsafe food additive"—and then concluding that unsafe food additives are also subject to seizure. It requires no citation of authority to demonstrate that courts ought not rewrite statutes.

While under certain circumstances a food additive can constitute a statutorily defined food, not all food additives are food. This proposition can be best illustrated by the concrete example of a food coloring agent. A food coloring agent constitutes a "food additive" because it is a "substance the intended use of which results . . . in its becoming a component or otherwise affecting the characteristics of any food." 21 U.S.C.

§ 321(s). It can also constitute a "food" because it is a "component" of food. Paper food-packaging material, however, could be considered a "food additive" in the sense that it is capable of "affecting the characteristics" of food, but it is not a food for it does not constitute a component of food. Indeed, it is evident that the definition of "food additive" is broader than that of "food" for the simple reason that the definition of food additive includes both food components and other materials affecting food, while the definition of food includes only components. Had Congress wished to include all food additives in the statutory definition of food, it would have done so by the simple expedient of adding "food additive" to the definition.

It was the failure of the courts below to remain faithful to the distinction between "food" and "food additive" which produced their statutory revision. Section 334(a)(1) of the Act permits seizure of "food" that is adulterated, not, as the FDA urged below, adulterated food additives without regard to whether they are components of food. Only where food additives are also food components are they subject to seizure.

II. "Public Protection" Does Not Justify Statutory Revision

The causative factor producing the statutory revision was a fear that implementation of the plain meaning of the statutory definition of food "would effectively deny FDA the means to protect the public from adulterated *food.*"[3] 525 F.2d at 1107 (emphasis added).

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[3] The assumption that a distortion of the statute was necessary for public protection is questionable. If any *food* contains a harmful level of PCB's, the FDA can and should seize the food and thereby protect the public.

Natick does not dispute that the Act is legislation entitled to a liberal construction to foster public protection. Nonetheless, this Court has frequently cautioned that the primary judicial duty is to "be faithful to the meaning of a statute" and that "Congress expresses its meaning by words." *Addison* v. *Holly Hill Fruit Products, Inc.*, 322 U.S. 607, 617 (1944). The words used by Congress to define "food" cannot be judicially transmogrified to include paper food-packaging materials if courts are to remain faithful to the principle that proper statutory construction requires refraining from the impulse "[t]o draw upon some unexpressed spirit outside the bounds of the normal meaning of words." *Ibid.*

Nor are these principles confined to legislation less imbued with public purpose than is the Act. Justice Frankfurter, speaking for this Court in *62 Cases, More or Less, Each Containing Six Jars of Jam* v. *United States*, 340 U.S. 593, 600 (1951), insisted that the Act's public purposes did not excuse judicial distortion of the plain meaning of its definitional terms:

> "In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop."

Congress has indicated that the FDA's seizure power stops with foods; and paper food-packaging material is not a food. This Court should enforce that prohibition.

CONCLUSION

For the foregoing reasons, petitioners respectfully request that the writ of certiorari be granted.

Respectfully submitted,

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April 23, 1976

CERTIFICATE OF SERVICE

I, Robert T. Lasky, a member of the Bar of this Court, hereby certify that, on April 23, 1976, I caused to be mailed first class, postage prepaid, three copies of the foregoing Petition for Writ of Certiorari to the United States Court of Appeals for the First Circuit to:

Thomas E. Kauper, Esq.
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.....
Robert T. Lasky

APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 75-1134

NATICK PAPERBOARD CORP.
and
CROWN PAPERBOARD CO., INC.,
Appellants,

v.

CASPAR W. WEINBERGER,
Secretary of Health, Education and Welfare,
and
ALEXANDER M. SCHMIDT,
Commissioner of Food and Drugs,
Appellees.

Appeal from the United States District Court for the District of Massachusetts

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(ANDREW A. CAFFREY, *United States District Judge*)
(389 F. Supp. 794)

Before COFFIN, *Chief Judge*
CAMPBELL, *Circuit Judge*, and
THOMSEN*, *Senior District Judge*

Jerome H. Heckman, with whom *Endicott Peabody, Christopher A. Hart, Peabody, Rivlin & Lambert, Paul T. Smith and Keller* and *Heckman* were on brief, for appellants.

Alan R. Bennett, Assistant Chief Counsel, Food and Drug Administration, with whom *Thomas E. Kauper*, Assistant Attorney General, Antitrust Division, United States Depart-

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* Of the District of Maryland, sitting by designation.

ment of Justice, *Gregory B. Hovendon*, Chief, Consumer Affairs Section, United States Department of Justice, *Robert V. Allen*, Attorney, Consumer Affairs Section, Department of Justice, and *Richard A. Merrill*, Chief Counsel, Food and Drug Administration, were on brief, for appellees.

November 26, 1975

THOMSEN, *Senior District Judge.* Plaintiffs appeal from a summary judgment for defendants, the Secretary of HEW and the Commissioner of Food and Drugs (collectively, FDA), which declared that they have the authority under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq. (the Act), to recommend seizure of paper food packaging material containing polychlorinated biphenyls (PCB's) in excess of 10 parts per million (ppm) as adulterated food. 389 F.Supp. 794 (D. Mass. 1975).[1]

PCB's are a group of toxic chemical compounds, which find their way into industrial waste, and thence into various products, including recycled paper products. If such a product is used for packaging food, PCB's are likely to migrate into the food unless the food is protected from such migration by an impermeable barrier.

Both plaintiffs manufacture paper and paper products, including paper packaging material from waste paper; they sell such material in interstate commerce, and some of it is used by their customers to make containers for packaging food. Plaintiffs argue that food packaging material is not "food" within the meaning of the Act, and therefore is not subject to seizure as "adulterated food", and that the notice of intended seizure is overbroad.

I

On July 6, 1973, FDA published a proposed regulation, intended to limit the presence of PCB's in human and

[1] See also 367 F. Supp. 885 (D. Mass. 1973) and 498 F.2d 125 (1 Cir. 1974).

animal foods by prohibiting, inter alia, PCB residues of more than 10 ppm in paper food packaging material intended for or used with human food, finished animal feed and any components intended for animal feeds, unless the paper food packaging material is separated from the food therein by a functional barrier which is impermeable to migration of PCB's. 38 F.R. 18096, 18101-02; 21 C.F.R. § 122.10 (a) (9).[2]

Plaintiffs and others filed objections to subsection (a) (9) of the proposed regulation, and its effectiveness was thereby stayed pending a hearing,[3] which has not yet been scheduled. However, on August 24, 1973, FDA announced that in the interim any paper food packaging material shipped in interstate commerce after September 4, 1973, containing PCB's in excess of 10 ppm, would be seized as "adulterated" in violation of sec. 402 of the Act, 21 U.S.C. sec. 342, which defines "adulterated food". See 38 F.R. 22794.

Plaintiffs' complaint herein sought both injunctive and declaratory relief against such seizures. Both were originally denied by the district court because it felt that it lacked authority to grant any relief. 367 F. Supp. 885 (D. Mass. 1973). We affirmed the denial of injunctive relief, but reversed the district court's judgment with respect to declaratory relief jurisdiction and remanded the case for further proceedings. 498 F.2d 125 (1 Cir. 1974).[4]

After a further hearing, the district court granted summary judgment for defendants (FDA), declaring "that they have the authority under the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A. § 301 et seq., to recommend seizure of paper food-packaging material containing poly-

[2] The regulation is quoted in 498 F.2d at 126.

[3] See 21 U.S.C. 371 (e) (2).

[4] We said, at p. 129: "Nothing in this opinion shall be deemed to bar the institution of seizures in the interim under § 334."

chlorinated biphenyls (PCB's) in excess of 10 parts per million as adulterated food." 389 F. Supp. at 798. Plaintiffs appeal from that judgment.

II

The following sections of the Act relating to adulterated food and food additives are material to the issues presented. All references are to sections of Title 21 of the U.S. Code.

Sec. 334(a)(1) and (b) permit seizure of "[a]ny article of food * * * that is adulterated * * * when introduced into or while in interstate commerce or while held for sale * * * after shipment in interstate commerce * * *."

Sec. 321(f) provides: "The term 'food' means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."

Sec. 342(a)(2)(C) states that a food is adulterated "if it is, or it bears or contains, any food additive which is unsafe within * * * the meaning of section 348."

Sec. 321(s) defines a "food additive" as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in * * * packaging * * * or holding food; * * *), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures * * * to be safe under the conditions of its intended use; * * *."

Sec. 348 (a) provides: "A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2) (C) of section 342 (a) of this title, unless—(1) * * *; or (2) there is in effect, and it and its use or intended use are in conformity with, a regulation

issued under this section prescribing the conditions under which such additive may be safely used." No such regulation upon which plaintiffs might rely is in effect. Therefore, if paper food packaging material containing PCB's in excess of 10 ppm is a food additive, it is unsafe within the meaning of sec. 348.

III

The affidavits before the district court justify the conclusions that PCB's are toxic, that they tend to migrate from paper packaging material to the contained food by a vapor phase phenomenon, that paper packaging material containing PCB's in excess of 10 ppm is not generally recognized as safe for packaging food for human consumption unless the food is protected from such migration by an impermeable barrier,[5] and that if so used, without such barrier, paper food packaging containing PCB's "may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of * * * food" within the meaning of sec. 321 (s).[6]

Since, therefore, paper food packaging material containing PCB's in excess of 10 ppm will in many instances be an "unsafe food additive" within the meaning of the Act, we proceed to the central issue of this case: whether such material is "adulterated food" under sec. 342 and thus, under sec. 334 (a) (1) and (b), subject to seizure by FDA.

Sec. 342 (a) (2) (C) provides: "A food shall be deemed to be adulterated—* * * if it is, or it bears or contains, any food additive which is unsafe within the meaning of sec. 348 of this title." Plaintiffs argue that, although PCB's may be introduced into food by migration from the packaging, such

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[5] Cf. *United States* v. *Articles of Food and Drug, . . . Coli-Trol 80, etc.*, 518 F.2d 743, 746 (5 Cir. 1975); *United States* v. *An Article of Drug "Bentex Ulcerine"*, 469 F.2d 875, 878-79 (5 Cir. 1972), *cert. denied*, 412 U.S. 938 (1973).

[6] See *United States* v. *Article of Food . . . Pottery . . . Cathy Rose*, 370 F. Supp. 371 (E.D. Mich. 1974).

introduction is not intentional and therefore the packaging is not "used for components" of food within sec. 321 (f) (3). FDA replies that intentional introduction is not required to meet the definition, and refers to the "food additive" definition in sec. 321 (s), quoted above in Part II of this opinion, and to the legislative history.

The food additive provisions of the Act were added by the Food Additive Amendment of 1958, P.L. 85-929, 72 Stat. 1784. Its basic purpose is to permit FDA to regulate the use of substances affecting food without first determining that they are in fact dangerous; the method is to require that such substances be established as safe before being used. A new sec. 348 was added, establishing a procedure for approval by FDA and permitting the agency to establish tolerance and other regulations to insure that these substances will be used safely. Until the FDA has acted, sec. 348 (a) provides that substances which meet the definition of "food additive" are deemed "unsafe".[7]

The protection of the public from unsafe food additives was accomplished by amending sec. 342 (a), defining "adul-

[7] This purpose of the Amendment was further elucidated in the Senate Report on the bill:

> ". . . we would point out first that under existing law the Federal Government is unable to prevent the use in foods of a poisonous or deleterious substance until it first proves that the additive is poisonous or deleterious. To establish this proof through experimentation with generations of mice or other animals may require 2 years or even more on the part of the relatively few scientists the Food and Drug Administration is able to assign to a particular problem. Yet, until that proof is forthcoming, an unscrupulous processor of foodstuffs is perfectly free to purvey to millions of our people foodstuffs containing additives which may or may not be capable of producing illness, debility, or death."

Report of the Senate Committee on Labor and Public Welfare, S. Rep. No. 2422, 85th Cong., 2d Sess., 1, 2 (1958).

terated food". Among other provisions, a new clause (2) (C) was added to sec. 342 (a), stating that a food shall be deemed adulterated "*if it is* or it bears or contains, *any food additive which is unsafe* within the meaning of section 409 [codified as 21 U.S.C. 348]" (emphasis added). No other means of prohibiting the unauthorized use of unsafe food additives was provided for in the Amendment; none was needed.[8] We conclude that "unsafe food additives", whether intentional or incidental,[9] are "adulterated food" under sec. 342 (a) (2) (C), and, therefore, may be

[8] Plaintiffs make the argument from syntax: "it", as used in § 342 (a) (2) (C), must first be food before it can be adulterated food. However, plaintiffs do not contend that unsafe food additives intended to be introduced into food may not be seized. We see no sound reason to believe that Congress intended to subject to seizure an unsafe substance reasonably expected to become a component of food through intentional mixing but to exempt from seizure an unsafe substance (in this case packaging material containing PCB's) which is likely to affect the characteristics of food by means of migration when such unsafe substance is put to its intended use.

[9] Both the House and Senate Reports on the Food Additive Amendment contain the following (H. Rep. No. 2284, 85th Cong., 2d Sess. 3 (1958); S. Rep. No. 2422, 85th Cong., 2d Sess. 4, 5 (1958)):

> "The legislation covers substances which are added intentionally to food. These additives are generally referred to as 'intentional additives'.
>
> "The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as 'incidental additives'.
>
> "The principal example of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food."

seized, subject to the provisions of sec. 334 (a) (1) and (b).[10]

It would defeat the policy of the Act to require, as plaintiffs contend, that FDA must wait until the unsafe food additive has actually entered or come in contact with food before it can be seized; it is enough that FDA has reasonable cause to expect that the additive will be used in such a way as to enter or otherwise come in contact with food. To wait until actual contamination occurs, in the warehouse of the food processor, on the shelf of a grocery store, or in a family kitchen would effectively deny FDA the means to protect the public from adulterated food. *United States* v. *Ewig Bros. Co., Inc.*, 502 F.2d 715 (7 Cir. 1974), *cert. denied*, . . . U.S. . . . (1975); *United States* v. *Article of Food* • • • *Pottery* • • • *Cathy Rose*, 370 F. Supp. 371 (E.D. Mich. 1974). See *United States* v. *Bacto-Unidisk*, 394 U.S. 784, 798 (1969).

IV

We do not hold, however, that FDA can properly take steps to seize any and all paperboard containing PCB's in excess of 10 ppm wherever it is located and whatever its intended use may be. The district court properly limited its judgment to paper *food packaging* material. We interpret this to mean that the FDA must be able to prove that any paperboard intended to be seized before it has actually been used as a container for food is either in the hands of a packager of food or in transit to, ordered by, or being pro-

[10] Prior court approval of a seizure by the FDA is not required, and, as we held on the previous appeal in this case, 498 F.2d at 127, no court may restrain a contemplated seizure. *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950). The seizure is by process pursuant to a libel for condemnation filed in a district court against "the article, equipment or other thing proceeded against", sec. 334 (b). The owner or other appropriate person may contest the condemnation, and recover the articles or their value if they were seized unlawfully.

duced with the intention that it be sold to a packager of food, or that its intended use otherwise meets the test of sec. 321 (s). If the packager or other claimant can show that the food placed in or to be placed in the paper container is or will be insulated from PCB migration by a barrier impermeable to such migration, so that contamination cannot reasonably be expected to occur, the paperboard would not be a food additive and would not be subject to seizure under the Act. So interpreted, the notice of intended seizure is not overbroad.

The judgment of the district court, as interpreted in this opinion, is

Affirmed.

APPENDIX B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

Civil Action No. 73-2988-C

NATICK PAPERBOARD CORP., ET AL.,

v.

CASPAR W. WEINBERGER, Secretary of Health, Education and Welfare, ET AL.

Opinion

March 4, 1975

CAFFREY, Chief Judge.

This matter came before the Court on remand from the Court of Appeals. In its opinion the Court of Appeals ruled that an order filed by this Court dismissing the complaint for lack of jurisdiction was correct as to so much of plaintiffs' complaint as sought injunctive relief, but was incorrect as to so much of the complaint as sought declaratory relief. The relief sought by plaintiffs is Summary Judgment with a Declaratory ruling that paper food-packaging material is not food under the Food, Drug and Cosmetic Act of 1938, as amended, and that such material is therefore not subject to the seizure, civil, injunctive, or criminal sanctions of the Food, Drug and Cosmetic Act of 1938, as amended.

After the issuance of the mandate by the Court of Appeals, counsel orally reargued defendants' motion for summary judgment as to the complaint for declaratory relief and both parties have filed extensive memoranda of law in support of their respective positions. After hearing, I rule as follows:

There is no issue of material fact which requires a trial herein. To assist in understanding the narrow area in which the parties are in disagreement a brief statement of the

Secretary's theory of the case and plaintiffs' rejoinder thereto would seem appropriate. The Secretary contends that the declaratory relief sought by plaintiffs should be denied and that this Court should rule that the Secretary can regulate the composition of paper materials used to package food which is shipped in interstate commerce, at least in cases where those packaging materials are of such a nature that the contents of the packaging material can migrate into the contents of the package, i.e., into the food itself. The Secretary's theory is that those food-packaging paper materials whose composition includes a substance called polychlorinated biphenyls (PCB's) may be proscribed by him because the PCB's, when present at a level of more than 10 parts per million, are a toxic substance. The Secretary contends that the PCB's can migrate into the food which the paper containing them is used to package. The Secretary further takes the position that food containing PCB's in excess of the stated level (10 parts per million) is a toxic substance and is adulterated.

Both parties agree that 21 U.S.C.A. § 334(a)(1) prohibits the introduction into interstate commerce of food which is adulterated. That section provides in pertinent part:

> "Any article of food . . . that is adulterated . . . shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States . . . within the jurisdiction of which the article is found."

Plaintiffs' position is that, properly construed, § 334(a)(1) only prohibits the introduction into interstate commerce of food which is adulterated. Plaintiffs specifically deny that the section reaches food-packaging material containing PCB's, on the grounds that food-packaging material is not "food" within the meaning of 21 U.S.C.A. § 321(f).

The Secretary specifically argues that such packaging materials should be construed as food within the meaning of § 321(f) and the Secretary also argues that packaging material containing PCB's in excess of 10 parts per million is a food additive within the meaning of 21 U.S.C.A. § 321 (s), which is unsafe for human consumption within the meaning of 21 U.S.C.A. § 348 and, therefore, an adulterated food within the meaning of § 342(a)(2)(C).

Basically, the controversy between the parties is as to whether or not food-packaging materials can properly be construed as food within the meaning of § 321(f). That section provides:

> "The term 'food' means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."

Section 321(s) defines food additives as follows:

> "The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, *packaging,* transporting, or holding food . . .) . . ." (Emphasis added.)

Section 321 was enacted in 1938 and some twenty years later the food additive amendment of 1958 was enacted. Significantly, this amendment contained a new provision that a food is adulterated "if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title." 21 U.S.C.A. § 342(a)(2)(C). The same amendment added the definition of food additive now contained in 21 U.S.C.A. § 321(s) quoted above. I rule that the clear, unambiguous language of Section

321(s) establishes that food-packaging materials may be found to be food additives. Cf. United States v. Ewig Bros. Co., Inc., 502 F.2d 715, 721 (7 Cir. 1974).

The broadly protective intent of this legislation appears from the legislative history thereof. The Senate Committee report contains the statement, "We want the record to show that in our opinion the bill is aimed at preventing the addition to the food our people eat of any substances the ingestion of which reasonable people would expect to produce not just cancer but any disease or disability." Sen. Rpt.No.2422, 85th Cong., 2d Sess. (1958), 3 U.S.Code Cong. & Admin.News, p. 5310 (1958). The legislative history further establishes that the House subcommittee analyzing the bill considered, and explicitly rejected on the ground of surplusage, a proposed amendment that would have brought "food additive" within the definition of "food." The subcommittee spokesman, Rep. John Bell Williams, stated:

> "It was the feeling of the Committee that such a provision would be surplusage since the present Food and Drug law, in section 201(f) [21 U.S.C.A. § 321 (f)] already defines 'food' as including all components thereof. Since substances which get into food incidentally in its manufacture, handling or packaging would be dealt with as a 'food additive' under the bill, there appears to be no need to have such substances also defined as a 'food.'" 104 Cong. Rec. 17, 418, Aug. 13, 1958.

From the foregoing, it may be fairly adduced that the committee intended that the same controls and regulations which apply to food also apply to food additives. This is consistent with Congress' concern that the Secretary be empowered to monitor and regulate anything traveling in interstate commerce which ultimately would be ingested by human beings, regardless of the label appended thereto.

In United States v. Dotterweich, 320 U.S. 277 at 280, 64 S.Ct. 134 at 136, 88 L.Ed. 48 (1943), the Supreme Court observed with reference to federal legislation in the area of food and drugs:

> "The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. . . ."

In 1968 that Court reaffirmed the principle that remedial legislation, such as the Food, Drug and Cosmetic Act, is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health and the Court also told us that this is a "well-accepted principle." United States v. Bacto-Unidisk, 394 U.S. 784, 798, 89 S.Ct. 1410, 22 L.Ed.2d 726 (1968).

The only case discovered specifically applying the philosophy of the *Bacto-Unidisk* case to the precise type of problem now before this Court resulted in a ruling favorable to the Secretary. In United States v. Articles of Food . . . Pottery . . . Contemporary Ironstone (Cathy Rose), 370 F.Supp. 371 (E.D. Mich.1974), the Secretary sought forfeiture of pottery dinnerware, alleging that it contained a food additive, lead, which the Secretary asserted was unsafe within the meaning of 21 U.S.C.A. § 342(a)(2)(C). The Government's theory in that case was that the lead

could migrate from the pottery to the food being served in it. The Court ruled in pertinent part:

> "The legislative history leading to the (1958) Food Additives Amendment of the Act shows a clear Congressional intent that substances which are subject to being ingested by human beings because of migration are 'food additives' and thus 'foods' within the meaning of the Act . . ." (at p. 373.)

Having in mind the statutory provisions quoted herein, the legislative history which I rule is supportive of the Secretary's position, and the attitudinal directives from the Supreme Court in *Dotterweich* and *Bacto-Unidisk, supra,* I rule that plaintiffs have not shown a right to the declaratory relief sought herein, and that defendants are entitled to summary judgment that they have the authority under the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A. § 301 et seq., to recommend seizure of paper food-packaging material containing polychlorinated biphenyls (PCB's) in excess of 10 parts per million as adulterated food.

Judgment accordingly.

No. 75-1540

In the Supreme Court of the United States

OCTOBER TERM, 1975

NATICK PAPERBOARD CORP., ET AL., PETITIONERS

v.

F. DAVID MATHEWS, SECRETARY OF HEALTH, EDUCATION AND WELFARE, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-9a) is reported at 525 F. 2d 1103. The opinion of the district court (Pet. App. 10a-15a) is reported at 389 F. Supp. 794.

JURISDICTION

The judgment of the court of appeals was entered on November 26, 1975. On February 17, 1976, Mr. Justice Brennan extended petitioners' time within which to petition for a writ of certiorari to April 23, 1976, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether the Food and Drug Administration has the authority to recommend seizure of food-packaging

material containing excessive amounts of a toxic chemical when such chemical combines with and adulterates food packaged in the material.

STATUTORY PROVISIONS INVOLVED

Pertinent provisions of the Federal Food, Drug and Cosmetic Act of 1938, 52 Stat. 1040, as amended, 21 U.S.C. 321 *et seq.*, are set forth at Pet. 2-3.

STATEMENT

Respondents, the Secretary of Health, Education and Welfare and the Commissioner of Food and Drugs ("FDA"), have determined that polychlorinated biphenyls (PCB's) are toxic chemicals that should not be present above a specified level in foods. On July 6, 1973, the FDA published a proposed regulation designed to limit the occurrence of PCB's in food. A provision of the regulation would prohibit PCB residues of more than ten parts per million in paper food packaging material unless such material is separated from the food contained therein by a functional barrier impermeable to the migration of PCB's.[1] This proposed regulation, which is not challenged here (Pet. 4, n. 1), has not yet became effective. On August 24, 1973, however, the FDA announced (38 Fed. Reg. 22794) that all paper food-packaging material containing PCB's in excess of the announced standard would be considered an adulterated food and thus subject to seizure (Pet. App. 2a-3a).

Petitioners, Natick Paperboard Corporation and Crown Paperboard Company, Inc., manufacture paper packaging material, some of which is used for food packaging.

[1]21 C.F.R. 122.10(a)(9).

Certain types of waste paper used by Natick in the manufacture of the packaging material contain PCB's. Petitioners sought a declaratory judgment[2] that FDA's August 24, 1973, notice was promulgated without statutory authority, because food packaging material could not be classified as a "food" subject to the seizure provisions of 21 U.S.C. 334(a)(1).

The district court granted respondents' motion for summary judgment. It held that food-packaging that may become a component or otherwise affect the characteristics of any food is a "food additive" as defined in 21 U.S.C. 321(s) (Pet. App. 12a-13a). Under 21 U.S.C. 342(a)(2)(C), a food is adulterated if it is, bears or contains any unsafe food additive. Food packaging containing excessive levels of PCB's may thus constitute an adulterated food subject to seizure. This application of the statute, the district court held, was consistent with the general congressional purpose, reflected in the legislative history, "to monitor and regulate anything traveling in interstate commerce which ultimately would be ingested by human beings, regardless of the label appended thereto" (Pet. App. 13a-15a).

The court of appeals unanimously affirmed (Pet. App. 1a-9a). It found that there was sufficient evidence to justify the district court's finding that food-packaging material containing PCB's in excess of 10 ppm is an "unsafe food additive" as defined in 21 U.S.C. 321(s),

[2]Petitioners initially sought both declaratory and injunctive relief, but the district court denied all relief on the basis that it lacked jurisdiction. 367 F. Supp. 885 (D. Mass.). The court of appeals affirmed the district court with respect to the injunction, but reversed and remanded the case for the district court to adjudicate the merits of the request for declaratory relief. 498 F. 2d 125 (C.A. 1).

348(a) (Pet. App. 4a-5a). It noted that in the Food Additives Amendment of 1958 (72 Stat. 1784), Congress expanded the definition of "adulterated food" to include any component of food that is an "unsafe food additive" (Pet. App. 5a-7a). Relying upon the Amendment's history, the court rejected petitioners' assertion that only those "unsafe food additives" that were intended to be mixed with foods could be considered "foods" within the meaning of the Act. Rather, it was sufficient if the intermixture resulted from the intended use of the additive (Pet. App. 7a, nn. 8 and 9). The court reasoned that limiting the seizure provisions of the Act to cases of intentional mixing of unsafe food additives and foods, or requiring the FDA to delay seizure until after contamination actually occurred, would be inconsistent with the statutory policy of protecting public health and safety (Pet. App. 8a). The court held, however, that the FDA may seize only paperboard containing excessive PCB's which is clearly intended for use as food packaging, and if the food is protected by a barrier impenetrable to PCB's, the food is not subject to seizure. So construed, the court held FDA's notice of seizure is not overbroad.

ARGUMENT

The decision of the court of appeals is correct and there is no reason for this Court to grant the petition.

1. Petitioners appear to concede (Pet. 7) that their food packaging material is a food additive under 21 U.S.C. 321(s). Nevertheless, they contend it may not be deemed an adulterated food subject to the seizure provisions of the Act because it is not intended to become intermixed as a component of food. That contention is contrary to the language of the statute, which treats an unsafe "food additive" as an adulterated "food," without regard to intended intermixture.

Section 321(s) declares that "'food additive' means any substance the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, (including any substance intended for use in * * * packaging * * * or holding food * * *)" if it is not generally recognized by qualified experts to be safe "under the conditions of its intended use." And 21 U.S.C. 342(a)(2)(C) provides that "[a] food shall be deemed to be adulterated * * * if it is * * * any food additive which is unsafe within the meaning of Section 348 of this Title * * *." For the purpose of this case, petitioners have not questioned FDA's findings that PCB's migrate from the packaging material to the packaged food, and that paper packaging materials are unsafe food additives when PCB residues in excess of 10 ppm are contained therein, 21 C.F.R. 122.10(a)(9) (Pet. 4, n. 1). Therefore, under 21 U.S.C. 342(a)(2)(c), food packaging material containing PCB residues in excess of 10 ppm is an adulterated food subject to seizure under 21 U.S.C. 334.

This conclusion is supported by the 1958 Amendment's legislative history. The House Subcommittee rejected a proposal to include "food additives" within the definition of food because the Act already defined "food" to include all components thereof (104 Cong. Rec. 17418 (1958)) (Pet. App. 13a). Congress assumed that when packaging material contains a substance which intermixes with food contained within it, it thereby becomes a component of, or affects, the food, and should therefore be treated like a food within the meaning of 21 U.S.C. 321(s), whether or not the intermixture was intended. See H.R. Rep. No. 2284, 85th Cong., 2d Sess. 3 (1958); S. Rep. No. 2422, 85th Cong., 2d Sess. 4, 5 (1958) (Pet. App. 7a, n. 9).

Petitioners not only fail to cite any contrary legislative history, but also fail to identify any policy that would support the distinction they seek to draw. From the perspective of protecting the public health and safety, it makes no difference whether the manufacturer intended an unsafe additive to intermix with a food, or whether the intermixture was unintended but was nevertheless an occurrence reasonably to be expected. In rejecting petitioners' argument that the relevant provisions of the Act turn upon whether the critical intermixture was intended, as distinguished from reasonably to be expected, the lower courts were correct in looking to the general purpose of the statute to corroborate their analysis of the statutory language and legislative history. As this Court stated in *United States* v. *Dotterweich,* 320 U.S. 277, 280, proper regard for the Act's purpose to protect life and health "should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely a collection of English words." See also *United States* v. *An Article of Drug * * * Bacto-Unidisk,* 394 U.S. 784, 798; *United States* v. *Sullivan,* 332 U.S. 689, 696-697.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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